## **MEMORANDUM**

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO

Director/NHLI Thru:Dep.D/NHLI DATE: Aug.5, 1973.

FROM:

Director/DTA

SUBJECT:

Key Personnel in Technological R and D.

The first observation on performance which was made by me after my arrival at NHLI was that the program lacked the expertise to judge (1) the adequacy of planned work scopes, (2) the precision of either protocols or performance, or (3) the conclusiveness of reports from contractors. Contractor after contractor was allowed to bungle ahead without the in-house scientific investigative capability in their establishments to avoid waste of time and assets or loss of opportunity. This could have been set aright by assiduous and knowledgeable setting of protocols (as called for by contract) and enlightened monitoring from NHLI\*.

For this reason the decision was made that proper expertise should be brought into the program. Dr. Sylvain Pitzele was planned as the first of five men but was the only man recruited before proscription of recruitment brought these plans for improvement to a halt. His performance, even though initially he was unfamiliar with the ways of the establishment, has been superb. The following are some of the projects which resound to his credit:

- 1) The critical evaluation of the Veno-Arterial Bypass System and the handling of it by the T and E's project dropped.
- 2) A critical evaluation of the Dow Capillary Membrane Oxygenator project as it stood essentially dropped. A variation on the design may prove of value.
- 3) A substantial contribution to the evaluation of the functioning of the T and E Facilities phasing out of those facilities.
- 4) Utilization of a laboratory in Building 28 to establish the feasibility of use of Persantin and similar drugs as anti-aggregational agents in connection with the various projects on mechanical handling of blood in DTA. Others had tried and failed, including a contractor of DTA.
- 5) Subsequent to the meeting of the Panel on Energy Sources and the Panel on Pumping at the end of May and the beginning of June, establishment of precise, scientifically sound work scopes and protocols for those

<sup>\*</sup> A few examples: The Veno-Arterial Bypass System at TECO, which would not have been conceived if a knowledgeable perfusionist had been involved; the Dow Capillary Membrane Oxygenator, with inclusion of material which had been proven thrombogenic; the MediPhysics oxygenator, which rested on principles already reported to be faulty; the Arco Nuclear engine, which rested on principles already shown inferior by TECO; the H-TAH pump, imposed on all engine developers without developmental studies on the pump, which now has a maximum bench life of 2 weeks; the loose-reined operation of the UBTL, with no substantial concept of a controlled experiment.

contractors to be continued in support. Quite apart from these protocols. these workshops with these contractors have generated patterns of approach to solutions of current problems which distinctly arose within DTA rather than with the contractors, and which are essential to solution of the problems at hand. Dr. Pitzele's participation and cooperation will be essential to satisfactory implementation of these studies.

The viability of a scientifically acceptable program of directed research and development depends upon the presence of this caliber of guidance from within NHLI. It is pathetic to have so little of this expertise. What there is must be nurtured and protected and used in the manner in which Dr. Pitzele has been utilized. Without such strength in the program to technological research and development to guide, coordinate, and monitor the work at hand, goal-oriented, directed research and development should revert fully to the grant mechanism, where scientific capability on an occasional basis suffices. In that case there would be no remnant of sooperation with industry, the bringing of scientific developments to clinical application would be delayed, and the utility of either Dr. Pitzele's or my background of investigational expertise to the program would be largely negated.

Dr. Pitzele's participation in the projects of the two Task Forces from the Advisory Committee of the DTA will guarantee an excellent pair of important surveys. It is, however, and extravagant use of the time of a man whose invaluable attention is so important to the performance of the program in technological development.

It had been my intent that the recruitment of Dr. Abbrecht for a year would prove an alternate means to broaden the scientific counsel given to individual contractors. The conference with him on Aug. 3 was as disturbing to me as it was unexpected in thrust. The importance of what he is to do is conceded, but it comes at the expense of what could be a markedly improved performance of the work in progress.

In view of these considerations, it is essential to the success of the program in technological research and development that we nurture the expertise we have and keep Dr. Pitzele with me in the newly streamlined program in a position in which he can contribute continuing scientific supervision over the contractual work in progress. Meuni